K112391

FUJIFILM

JUL 26 2012

510(k) Summary

Date: February 27, 2012

Submitter's Information:

Fujifilm Medical Systems U.S.A., Inc.
10 High Point Drive
Wayne, NJ 07470 USA

Contact Person:

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Identification of the Proposed Device:

Proprietary/Trade Name: Fujinon Colonoscopes, EC-530HL2 and EC-530LS2
Common Name: Colonoscope
Device Class: Class 2
Review Panel: Gastroenterology/Urology
Classification Information:

Classification Name:	CFR Section	Product Codes
Colonoscope and accessories, Flexible/Rigid	21 CFR 876.1500	FDF

I. INDICATIONS FOR USE

This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

II. DEVICE DESCRIPTION

Fujinon Colonoscope EC-530HL2 and EC-530LS2 are modified versions of our previously-cleared Fujinon G5 Colonoscopes, Model EC-450HL5 and EC-250HL5 as described in K041903. The modified models are intended for observation, diagnosis, and endoscopic treatment of the lower digestive tract, which includes rectum, sigmoid colon, and large intestine, which remains the same as K041903.

The endoscopes are comprised of three general sections: an operation section, a flexible portion and an umbilicus. The operation section controls the angulation (up/down/left/right) of the distal end of the endoscope. The flexible insertion portion contains glass fiber bundles, several channels and a charged couple device (CCD). The

glass fiber bundles allow light to travel through the endoscope to illuminate the body cavity thereby providing enough light to the CCD to capture an image and display the image on the monitor. The endoscope also contains several channels to deliver air/water, provide suction and a working channel. The forceps channel or working channel is used to introduce endoscope accessories such as biopsy forceps. The umbilicus contains electronic components needed to operate the endoscope when plugged to the video processor and the light source.

The modified models are used in combination with Fujinon's video processor, light source, monitor, cart, foot switch, endoscope accessories and other peripheral devices.

III. SUMMARY OF STUDIES

Fujinon Colonoscope EC-530HL2 and EC-530LS2 were evaluated in accordance with following safety and performance requirements in addition to the applicable quality system regulations:

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
IEC60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC60601-1-2	Medical electrical equipment - Part 1-2: General requirements for the basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment
ISO10993	Biological evaluation of medical devices

The reprocessing instructions were updated and validated using a third party lab. No clinical test was conducted.

IV. SUBSTANTIAL EQUIVALENCE

Fujinon Colonoscopes EC-530HL2 and EC-530LS2 are substantially equivalent to the following device:

Legally Marketed Device	510(k) #
Fujinon G5 Colonoscopes, Model EC-450HL5 and EC-250HL5	K041903

EC-530HL2 and EC-530LS2 colonoscopes have the same indications for use as the legally marketed device. The minor dimensional changes, material changes and re-location of the water jet inlet do not adversely affect the safety and effectiveness of the subject colonoscopes.

V. CONCLUSION

Fujinon Colonoscopes EC-530HL2 and EC-530LS2 are substantially equivalent to the legally marketed device and conforms to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Gina Walljasper
Director Quality and Regulatory Compliance
Fujifilm Medical Systems U.S.A., Inc.
10 High Point Drive
WAYNE NJ 07470

JUL 26 2012

Re: K112391
Trade/Device Name: Fujinon Colonoscopes EC-530HL2 and EC-530LS2
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: July 25, 2012
Received: July 25, 2012

Dear Ms. Walljasper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K112391__

Device Name: Fujinon Colonoscopes EC-530HL2 and EC-530LS2

Indications for Use:

This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

Prescription Use__X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112391